

Food and Drug Administration, HHS

§ 520.1120a

(2) Each bolus contains 2.5 grams griseofulvin.

(3) Each tablet contains 125 or 500 milligrams griseofulvin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 000061 for use of products described in paragraph (a) for use as in paragraph (d) of this section.

(2) No. 059130 for use of the powder described in paragraph (a)(1) for use as in paragraphs (d)(1)(i)(A) and (d)(1)(ii) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use—(1) Horses—(i) Amount and indications for use—(A)* For equine ringworm infection caused by *Trichophyton equinum* or *Microsporium gypseum*, administer soluble powder described in paragraph (a)(1) of this section daily as a drench or as a top dressing on feed for not less than 10 days as follows: adults, 2.5 grams; yearlings, 1.25 to 2.5 grams; and foals, 1.25 grams.

(B) For treating ringworm infection caused by *T. equinum*, administer boluses described in paragraph (a)(2) of this section daily for not less than 10 days as follows: adults, 1 bolus; yearlings, one-half to 1 bolus; and foals, one-half bolus.

(ii) *Limitations.* Not for use in horses intended for food.

(2) Dogs and cats: (i) *Amount.* 125- and 500-milligram tablets administered orally as follows:

(A) Daily (single or divided) dose:

| Body weight (pounds) | Dosage (milligrams) |
|----------------------|---------------------|
| Up to 6 | 62.5 |
| 6 to 18 | 125 |
| 18 to 36 | 250 |
| 36 to 48 | 375 |
| 48 to 75 | 500 |

(B) Weekly (single) dose: If experience indicates that treatment is more effective for the drug given in large doses, administer at intervals of 7 to 10 days, a dose equal to 10 milligrams/pound of body weight × body weight × number of days between treatments. Dosage should be adjusted according to response. Administer additional dose after the animal is free of infection.

(ii) *Indications for use.* For treatment of fungal infections of the skin, hair,

and claws caused by *Trichophyton mentagrophytes*, *T. rubrum*, *T. schoenleini*, *T. sulphurem*, *T. verrucosum*, *T. interdigitale*, *Epidermophyton floccosum*, *Microsporium gypseum*, *M. canis*, *M. audouini*.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 42948, Sept. 29, 1976; 43 FR 28458, June 30, 1978; 52 FR 7832, Mar. 13, 1987; 54 FR 30205, July 19, 1989; 71 FR 38073, July 5, 2006]

§ 520.1120 Haloxon oral dosage forms.

§ 520.1120a Haloxon drench.

(a) *Chemical name.* 3-Choloro-7-hydroxy-4-methylcoumarin bis (2-chloroethyl) phosphate.

(b) *Specifications.* Haloxon assay of not less than 96 percent by infrared spectrum at 8.62 microns.

(c) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(d) *Special considerations.* Do not use any drug, insecticide, pesticide, or other chemical having cholinesterase-inhibiting activity either simultaneously or within a few days before or after treatment with haloxon.

(e) *Related tolerances.* See § 556.310 of this chapter.

(f) *Conditions of use.* It is used as a drench as follows:

(1) *Cattle—(i) Amount.* 141.5 grams per packet.

(ii) *Indications for use.* Control of gastrointestinal roundworms of the genera *Haemonchus*, *Ostertagia*, *Trichostrongylus*, and *Cooperia*.

(iii) *Limitations.* (a) Dissolve each packet in 32 fluid ounces of water and administer as follows:

| Weight of animal (pounds) | Dose (fluid ounces) |
|---------------------------|---------------------|
| Up to 100 | 1/2 |
| 100 to 150 | 3/4 |
| 150 to 200 | 1 |
| 200 to 300 | 1 1/2 |
| 300 to 450 | 2 |
| 450 to 700 | 3 |
| 700 to 1,000 | 4 |
| 1,000 to 1,200 | 5 |
| Over 1,200 | 6 |

(b) Do not treat within 1 week of slaughter; do not treat dairy animals